K081766

AUG - 8 2008

510(k) Summary of Safety and Effectiveness
Gyrus ACMI Incorporated
Gyrus ACMI Inc. PKS Omni Instrument

General Information

Manufacturer:	Gyrus ACMI Incorporated 136 Turnpike Rd. Southborough, MA 01772-2104
Contact Person:	Lorraine Calzetta
Date Prepared:	June 12, 2008

Device Description

Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400), Class II General and Plastic Surgery Panel
Trade Name:	Gyrus ACMI Inc. PKS Omni Instrument
Generic/Common Name:	Electrosurgical Instruments

Predicate Device

Gyrus Medical Inc. Zip Wing Cutting Dissector	K023493
Gyrus Medical Open Forceps	K024286
Gyrus Medical Plasma Seal	K061975
Gyrus Medical Plasmacision and Plasmablend Electrodes	K050460
Valleylab Ligasure Sealing System/ Ligasure V	K031011
Gyrus General Purpose Electrosurgical Generator	K050550

Intended Uses

The Gyrus ACMI Inc.PKS Omni Instrument is intended for electrosurgical coagulation, mechanical grasping and dissection of tissue, and sealing of vessels up to 3mm, during the performance of laparoscopic and general (open) surgical procedures. It is intended for use with the Gyrus ACMI G400 workstation cleared under K050550.

Device Description

The PKS Omni Instrument is a single-use device with a classic laparoscopic scissor-type layout, with a 5mm shaft available in several lengths from 15 to 45cm, supporting symmetrically opening steel jaws. These are curved in a manner similar to Maryland forceps and other laparoscopic graspers, and contain bipolar electrosurgical elements that allow coagulation, cutting and vessel sealing. It is intended for use with the Gyrus ACMI G400 workstation

Technological Characteristics and Substantial Equivalence

Like the predicate Zip Wing cleared under K023493, the upper and lower jaws contain the electrical elements that when placed at the desired tissue site, induce the cutting or coagulating/sealing tissue effect as the applicable generator mode is actuated.

The device is a refinement of already proven existing technology, Gyrus's PlasmaKinetic (PK) technology developed for dry field surgery (K050460). It relies upon simultaneous contact of both active and return electrodes of the bipolar device with the tissue. Other Gyrus devices use this principle in two modes to achieve cutting and coagulation effects. The Device is constructed of similar materials as other Gyrus ACMI electrosurgical devices.

The PKS Omni is intended to offer cutting and coagulation using bipolar electrosurgical energy application in a manner similar to other devices on the market (such as Gyrus ACMI Open Forceps (K024286,) and Valley Lab Ligasure V (K031011) for coagulation of vessels, and Plasmacision electrodes (K050460) for bipolar cutting and surface coagulation of tissue).

Summary of Safety and Effectiveness

The Gyrus ACMI Inc. PKS Omni Instrument, as described in this submission, is substantially equivalent to the predicates in intended use, principles of operation and fundamental scientific technology and raises no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gyrus ACMI, Inc.
% Ms. Lorraine Calzetta
Regulatory Affairs
136 Turnpike Road
Southborough, Massachusetts 01772

AUG - 8 2008

Re: K081766
Trade/Device Name: Gyrus ACMI Inc. PKS Instrument
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 12, 2008
Received: June 20, 2008

Dear Ms. Calzetta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

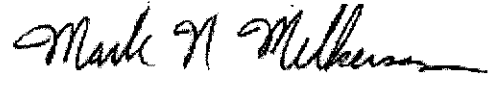
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Device Name: Gyrus ACMI Inc. PKS Omni Instrument

510(k) Number: K081766

Indications for use:

The Gyrus ACMI Inc. PKS Omni Instrument is intended for electrosurgical coagulation, mechanical grasping, and dissection of tissue, and sealing of vessels up to 3mm, during the performance of laparoscopic and general (open) surgical procedures when used in conjunction with the Gyrus ACMI G400 workstation.

Prescription Use: __ X __ OR Over-the-Counter Use: _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K081766